

## PATENT APPLICATION

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## DATA CAPTURE AND MANAGEMENT SYSTEM

BY INVENTOR

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## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is cross-referenced to and claims priority from U.S. Provisional application 60/288,620 filed 05/04/2001, which is hereby incorporated by reference.

## FIELD OF THE INVENTION

This invention relates generally to computer software and the Internet. More particularly, the present invention relates to a data capture and management system.

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## BACKGROUND

Data management has become not only more involved due to higher data volumes, but also more important in research and development due to a shortened time to market in increasingly demanding and more global markets. This is particularly true in the age of faster computers

and the Internet where it has become easier to acquire, exchange and process data. For example, about forty percent of the research and development expenses of pharmaceutical companies is used for clinical trial data capture and management. Clinical trials usually generate a significant amount of data that requires the effort of a large team of people including physicians, clinical data managers, data entry personnel, programmers, and statisticians. Each member of the team performs a specific function vital to the quality of the end database. A system that enables one to concurrently access and process data at the several stages of the database lifecycle enhances the overall work process and accelerates database development.

The use of off-the-shelf database packages will probably be capable of processing all the data captured in, for instance, a clinical trial, product database, or a weather forecast system. However, these packages usually have difficulty being accepted by the various different types of users. One of the reasons is that these packages become too involved and complicated to interact with. It is not uncommon for users to loose track of the status of entered data. In addition, current database management systems commonly lack flexibility, scalability, and performance in order to connect to its users. Therefore, to get a higher acceptance rate by its users and become a more useful tool, there is a strong demand to develop future data capture and management systems that include better ways to organize data as well as novel techniques to quickly review the status of entered data.

Accordingly, there is a need to develop a more practical and useful data capture and management system that facilitates user cooperation and global operability.

## SUMMARY OF THE INVENTION

The present invention provides a data capture and management system that is accessible by a computer or the Internet. The system tangibly embodies a program of instructions that are executable by a computer to perform method steps for data capture and management. In accordance with exemplary embodiments, the present invention includes a plurality of tabular forms, thereby representing a multi-dimensional database system. The present invention could include just one tabular form, however, most applications require several corresponding tabular forms. Each tabular form contains data in a plurality of cells. Other types of data representations could also be included. Each cell could correspond to a corresponding tabular form. The data between corresponding tabular forms could be displayed by activating a cell of interest in a tabular form of interest. A particular cell of interest is activated by at least two different means of activating. For example, a first means and a second means of activating a cell of interest which need to distinguishable from each other. Means of activating a cell are, for instance, but not limited to, a click, a double-click, roll-over, or other means of activating a cell. The first means of activating a cell of interest in a tabular form of interest is used to display, for instance, a data sheet. Other types of data representations could also be used. The data sheet displays, for instance, a data summary or a selection of data that corresponds to the data from a corresponding tabular form. The corresponding tabular form is part of the plurality of tabular forms and is associated to the cell of interest. The second means of activating a cell of interest in a tabular form of interest is used to display, for instance, the corresponding tabular form.

In addition, the present invention provides various ways of reviewing the status of the entered data. For instance, it might be important to know that, after data has been entered in, for instance, a tabular form of interest, the form could still require some additional data to be filled out in some of the cells. Other examples that might be of interest for review are, for

example, but not limited to, the information that a particular tabular form needs to be verified, statistical parameters need to be calculated, the form contains erroneous data, or the form contains data exceeding predefined boundaries. The different ways of reviewing the status of the data in a form or data sheet is accomplished by different descriptors, which is accomplished by providing a cell with a descriptor. Examples of descriptors are, for instance, but not limited to, a plurality of signs, a plurality of colors, a plurality of tags, or a plurality of statistical parameters. In case of colors, different color codes are used to indicate the status of data of a tabular form, which is indicated by that color of a cell.

The data capture and management system could be used on a single computer, but could also be part of an internet-based network that contains a central hub and one or more agents or computers connected to the central hub to perform at least one data capture and management operation. In this case, the system also provides a web-browser for online communication between a user using one or more agents and the central hub. Besides an online connection, the system, could also be used offline in which a local web-browser is provided for offline communication between a user using one or more agents and a local server. The system also provides mechanisms for synchronizing at least one data capture and management operation between the local server and the central hub.

In addition, the system includes a manager with a plurality of tools to manage at least one data capture and management operation. The system also includes different mechanisms to display information of at least one data capture and management operation as well as different mechanisms to manipulate data in the plurality of cells. For instance, these manipulation mechanisms include, but are not limited to, the basic computer data operations such as copy, cut, paste, edit, undo, drag, or delete as well as mathematical operations. In addition, data could be manipulated by the use of, for example, but not limited to, radio buttons, sliders, data

menus, click boxes, or the like. Manipulation of data is possible at the tabular form level as well as the data sheet level of the system

In view of that which is stated above, it is the objective of the present invention to provide a data capture and management system with a plurality of tabular forms that represents a multi-dimensional database system.

It is another objective of the present invention to provide a data capture and management system in which each tabular form contains a plurality of cells, wherein at least one cell of interests can be selected that corresponds to another tabular form.

It is yet another objective of the present invention to provide a data capture and management system that contains at least two different means of activating a cell of interest to display data from the tabular form that corresponds to the cell of interest. The data from the corresponding tabular form could be displayed partially as a data sheet or displayed entirely as a corresponding tabular form.

It is still another objective of the present invention to provide a plurality of descriptors for a cell of interest to provide status information of the data contained in a corresponding tabular form.

It is still another objective of the present invention to provide a flexible data capture and management system in which data can be quickly interpreted and manipulated.

It is another objective of the present invention to integrate the data capture and management system in a local as well as a global network connected to a central hub, wherein the system

could be used on different computers and act as different agents that interact with the central hub.

The advantage of the present invention over the prior art is that the system enables one to capture and manage large amounts of multidimensional data, such as, but not limited to, data obtained in clinical trials, by incorporating mechanisms for easy access and review at the different levels of the multidimensional database. Another advantage is that the present invention uses different descriptors that enable one to quickly review and interpret large data sets.

### BRIEF DESCRIPTION OF THE FIGURES

The objectives and advantages of the present invention will be understood by reading the following detailed description in conjunction with the drawings, in which:

- FIG. 1** illustrates the general concept of a plurality of tabular forms with a plurality of cells according to the present invention;
- FIG. 2** illustrates a data capture and management system according to the present invention;
- FIG. 3** illustrates a tabular form with a data sheet according to the present invention;
- FIG. 4** illustrates a corresponding tabular form according to the present invention;
- FIG. 5** illustrates a corresponding tabular form with a data sheet according to the present invention;
- FIG. 6** illustrates a corresponding tabular form of descriptor data including a data sheet according to the present invention;
- FIG. 7** illustrates a corresponding tabular form with a data sheet that allows data manipulation according to the present invention; and

**FIG. 8** illustrates an Internet setup for utilizing the data capture and management system according to the present invention.

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## DETAILED DESCRIPTION OF THE INVENTION

Although the following detailed description contains many specifics for the purposes of illustration, anyone of ordinary skill in the art will readily appreciate that many variations and alterations to the following exemplary details are within the scope of the invention. Accordingly, the following preferred embodiment of the invention is set forth without any loss of generality to, and without imposing limitations upon, the claimed invention.

The present invention provides a data capture and management system that is accessible by a computer or the Internet. The system tangibly embodies a program of instructions that are executable by a computer to perform method steps for data capture and management. In accordance with several exemplary embodiments, the present invention includes a plurality of tabular forms and represents a multi-dimensional database system. **FIG. 1** shows the general concept of a plurality of tabular forms **10**. Each tabular form in **10**, e.g. **100**, **130**, **160**, and **180**, contains a plurality of cells. For instance, tabular form **100** contained cells **110** and tabular form **130** contained cells **140**. The present invention is not limited to a data representation in cells **110**, whereas other forms of data representation could also be used. Cells **110** and **140**, for example, could represent data in terms of number, letters, images, and the like. A cell of interest **120** in a tabular form **100** could correspond to a corresponding tabular form **130** and is a selected cell by the user from cells **110**. The corresponding tabular form **130** also contains a plurality of cells **140**. The present invention could include just one tabular form, however, most applications require several corresponding tabular forms, thereby creating a complex and multidimensional data capture and management system. The idea is

that a cell of interest **120** represents a corresponding tabular form **130**, as is discussed in more detail below. In the most extensive case, all cells **110** of tabular form **100** could represent a corresponding form, thereby creating a complex and multi-dimensional system. For instance, a clinical trial database is such a complex and multi-dimensional system, wherein each cell

5 **110** could represent a particular client or patient and test date. Each cell **110** is then a cell of interest like cell **130** and will then correspond to a corresponding tabular form such as **130** that corresponds to **120**. A corresponding tabular form **130** could then contain, for instance, all the data for a particular client or patient. Another example is that corresponding tabular form **130** could contain specific medical data of that particular client or patient. The present invention is not limited to a clinical trial database systems, which is presented as an exemplary embodiment, as it could also be used for product or inventory data management, weather database systems, pharmaceutical drug database systems, and the like. The present invention is also not limited to the number of cells **110** that correspond to a corresponding tabular form **130**. A single cell **110** or a plurality of cells **110** could be associated to

10 subsequent or corresponding tabular forms. For example, cell **170** could be selected as a cell to correspond to tabular form **180**. Furthermore, the corresponding tabular form **130** could also contain a selected cell of interest **150** that corresponds to yet another level with a corresponding form **160**. Thereby, the system encompasses a cascading mechanism of tabular forms at different levels. The general idea is that this system enables one to manage and capture data from a global to a more specific perspective and level of detail, wherein the first tabular form **100** represents the subsequent and corresponding tabular form **130** in a global sense by just one cell, for instance **120**, whereas the corresponding tabular form **130** provides more detail to the user in its plurality of cells **140**.

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25 **FIG. 2** shows an exemplary embodiment of a clinical trial data capture and management system **200**. Tabular form **210** contains a plurality of cells. In this particular example, the



cells are used for different purposes such as patient ID **220**, patient number **221**, patient inclusion data **222**, or clinical trial test data **223**. As one skilled in the art might readily acknowledge, many different types of data could be represented in each cell in tabular form **210** as is discussed below in more detail.

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The present invention provides various ways of reviewing the status of the entered data in a tabular form of interest. For instance, it might be important to know that after data has been entered in, for instance, a tabular form **210**, the form could still require some additional data to be filled out in some cells. Referring back to **FIG. 1**, it is important to realize that the entered data could either be done at the first level, which is tabular form **100**, or at the subsequent/corresponding level, which is for instance tabular form **130**, **160** or **180**. Other examples that might be of interest for review are, for example, but not limited to, the information that a particular tabular form needs to be verified, statistical parameters need to be calculated, the form contains erroneous data, or the form contains data exceeding predefined boundaries. Referring back to **FIG. 2**, the different ways of reviewing the status of the data in form **210** is accomplished by different descriptors, for example, and not limited to, **230A**, **230B**, **230C** **230D**, and **230E**, which is accomplished by providing a cell of interest **240** with a descriptor **230D**. As shown in the particular example of **FIG. 2**, the information given by a descriptor could be “missing data” **230A**, “completed” **230B**, “flagged data” **230C**, invalid data” **230D**, and “validated on site” **230E**. Examples of descriptors are, for instance, but not limited to, a plurality of signs, a plurality of colors, a plurality of tags, or a plurality of statistical parameters. In case of colors, different color codes are used to indicate the status of data of a tabular form, which is indicated by that color of a cell.

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As shown in **FIG. 2**, the data capture and management system **200** includes a manager **250** with a plurality of tools **260** to manage at least one data capture and management operation.

Examples of tools **260** are, for instance, but not limited to, different folders with standard computer software means to manage at least one database, a user guide, technical support, or the like. The system also includes different tools **260** to display information of at least one data capture and management operation. In addition, as is discussed below, the manager **250** also contains tools **260** to utilize the data capture and management system **200** on either a single computer, as well as part of an internet-based network.

As discussed above with respect to **FIG. 1**, the data between corresponding tabular forms could be viewed by activating a cell of interest in a tabular form of interest. In fact, a particular cell of interest could be activated by at least two different means of activating. For example, a first means and a second means of activating a cell of interest. The first means of activating a cell is, for instance, but not limited to, a click, a double-click, roll-over, or other means of activating a cell. The activation could be accomplished by a computer mouse, by a touch to a screen, a remote device, or the like. **FIG. 3** shows tabular form **310** which is identical to tabular form **210** in **FIG. 2**. However, tabular form **310** also shows data sheet **320**. Data sheet **320** is displayed by a first means of activating a cell of interest **330** in a tabular form of interest **310**, such as, for instance, a roll-over. The present invention is not limited to the example of a data sheet **320**, since other types of data representations could also be used, such as, for instance, images, buttons, hyperlinks, or the like. The data sheet **320** displays, for instance, a data summary or a selection of data that corresponds to the data from a corresponding tabular form. In this particular embodiment referring to a clinical trial database, cells **340** in data sheet **320** could, for instance, represent and summarize specific data related to visit 1 **350** of patient **360**. The tabular form **310** as well as the data sheet **320** could both contain different descriptors **370** as discussed above to enable a user to quickly review the status of the entered data.

A second means of activating a cell of interest in a tabular form of interest is used to display, for instance, the corresponding tabular form. The second means of activating a cell is selected from the same group, but not limited to, as the first means of activating the cell of interest with the requirement that first and second means are different and distinguishable. As an exemplary embodiment, the same cell 330 could be activated by a second means, such as a click, to display the corresponding tabular form. As an exemplary embodiment, as shown in FIG. 3, a cell of interest 390 for patient 380 is selected to display a corresponding tabular form 410 as shown in FIG. 4. The corresponding tabular form 410 contains more detailed data than the tabular form 310. According to the specific embodiment of a clinical trial database, corresponding tabular form 410 contains data for patient 420 (same patient as 380 in FIG. 3) specific to different visits or tests 430. Again, the tabular form 410 could contain different descriptors 440, as discussed above, to enable a user to quickly review the status of the entered data. As mentioned above, in each tabular form, a cell of interest could be selected and activated by a first or second means. Therefore, in corresponding tabular form 410, cell of interest 450 could be selected and activated to display either a subsequent/corresponding tabular form or a data sheet. FIG. 5 shows the exemplary embodiment wherein cell of interest 520 in corresponding tabular form 510 is activated. Note that cell of interest 520 in corresponding tabular form 510 is the same as cell of interest 450 in corresponding tabular form 410 in FIG. 4.

In addition to a first and a second means of activating a cell of interest, it might in some cases or applications be necessary to provide additional means, e.g. a third means, of activating a cell of interest. In other words, the present invention also includes one or more additional means of activating a cell of interest. The important aspect to consider is that the different means of activating a cell of interest should be distinguishable from each other, as discussed above.

The data sheet **530** displays, for instance, a data summary or a selection of data that corresponds to the data from a subsequent/corresponding tabular form. In this particular embodiment referring to a clinical trial database, cells **540** of data sheet **530** could, for instance, represent and summarize specific data related to vital signs **550** of patient **560**. The tabular form **510** as well as the data sheet **530** could both contain different descriptors **570**, as discussed above, to enable a user to quickly review the status of the entered data.

**FIG. 6** is yet another example of an embodiment on how tabular forms and data sheets could interact. **FIG. 6** shows tabular form **610**, which classifies descriptor data from a plurality of different tabular forms in cells **620**. The exemplary embodiment shows, for instance, but not limited to, a variety of different clusters of cells according to “confirmed data” **630A**, “flagged data” **630B**, “validated data” **630C**, and “invalid data” **630D**. Again, cells **620** in tabular form **610** could be selected, for example, cell **630** could be selected to display data sheet **640**. In this particular example, data sheet **640** is a form **650** containing cells **660** to display general information about a patient **670** that corresponds to the cell of interest **630**. Again, the tabular form **610**, as well as the data sheet **640**, could both contain different descriptors, as discussed above, to enable a user to quickly review the status of the entered data.

The data capture and management system of the present invention also includes different mechanisms to manipulate data in each of the plurality of cells. For instance, these manipulation mechanisms include, but are not limited to, the basic computer data operations such as copy, cut, paste, edit, undo, drag, or delete, as well as mathematical operations. Such operations are utilized at the tabular form level as well as the data sheet level of the system. **FIG. 7** shows an exemplary embodiment in which data could be entered in data sheet **720** in

tabular form **710**. In the exemplary embodiment of a clinical trial, **FIG. 7** shows a data sheet **720** with a variety of vital signs **730** of a patient **740**. For instance, cell **750** requests a systolic blood pressure, for which the value could be entered in **760A** and the units in **760B**. As one skilled in the art might readily acknowledge, a wide variety of other techniques of entering data, rather than typing, could be employed, including, but not limited to, predefined radio buttons, sliders, menus, or equivalents thereof. In addition, the embodiment of a clinical trial is presented for exemplary purposes only and the present invention is not limited to clinical data as discussed above in which it could used also encompass product or inventory data, weather data, pharmaceutical drug data, and the like.

Furthermore, various types of mathematical operations could be carried out before data is displayed in a cell. It might, for instance, be important to convert data to a different unit (e.g. miles to km, cm to inches), change currency (dollars to French francs), perform a calculation based on a model or set of equations, or equivalents thereof. These mathematical operations are not limited to the level of tabular forms or whether the data concerns a data sheet of tabular form. An example of a calculation related to clinical trials is, for instance, but not limited to, the calculation of body surface area from height and weight. As one skilled in the art might readily appreciate, many different types of calculations can be included.

In addition, as is mentioned above, manager **250** in **FIG. 2** also contains tools **260** to utilize the data capture and management system **200** on either a single computer **820A**, now referring to **FIG. 8** , as well as part of an internet-based network **800** that contains a central hub **810** and one or more agents or computers (**820A**, **820B** ... **820N**) connected to central hub **810** to perform at least one data capture and management operation. In this case, the system also provides a web-browser for online communication **830** between a user using one or more agents **820A**, **820B** ... **820N** and the central hub **810**. Online communication is, for instance,

provided through a standard Web browser using an Internet service provider, an Intranet network system, or equivalents thereof. Besides an online connection, the system, could also be used offline in which a local web-browser is provided for offline communication between a user using one or more agents 820A, 820B ... 820N and a local server stored on each of the agents 820A, 820B ... 820N. Examples of a local web-browser are, for instance, a Local Area Network (LAN), a local server running on user's computer, or equivalents thereof. The system also provides mechanisms for synchronizing at least one data capture and management operation between the local server and the central hub. Synchronization is important when more than one user operates on the same database.

The present invention has now been described in accordance with several exemplary embodiments, which are intended to be illustrative in all aspects, rather than restrictive. Thus, the present invention is capable of many variations in detailed implementation, which may be derived from the description contained herein by a person of ordinary skill in the art. All such variations are considered to be within the scope and spirit of the present invention as defined by the following claims and their legal equivalents